Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

March 2, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 03D-0386, Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical cGMP.

Pfizer would like to acknowledge the effort put forth by the FDA in the publication of the Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical cGMP.

Pfizer supports the necessity for and actively encourages open debate and discussion with the investigator during the inspection. However, even with good communication, there may be instances where it is unclear which information is needed to answer an investigator's questions and concerns. The site may not understand the request until the FDA Form 483 is written and issued. Pfizer proposes to allow the submission of additional information at the Tier 1 and/or Tier 2 Levels as supporting information. This is particularly true if questions are raised during the activities of the Dispute Resolution Panel. Additional information, as distinguished from new information, should be considered for a fully knowledgeable review and resolution of issues.

Pfizer appreciates the opportunity to provide the attached comments to clarify and strengthen the proposed guideline.

Sincerely,

Maria Guazzaroni, Ph.D.
Director/Team Leader
Regulatory Monitoring
Global Manufacturing Compliance
Pfizer Inc.